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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SEHARASEYON, JEGATHEESAN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,736	EATON ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6,11-14 and 16-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4-6,12-14 and 16-31* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/4/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment and Declarations under 37 CFR § 1.132, both submitted 4 April 2005, have been entered. Claims 1-3, 7-10 and 15 are cancelled. Claims 4-6 and 14 have been amended. Claims 21-31 have been added. Claims 4-6, 11-14 and 16-31 are under examination in the Instant Application.

2. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

3. Applicants changing the title is acknowledged.

4. Applicants have provided a copy of the sequence listing in response to the "Notice to Comply".

5. Applicants request for correction of inventorship under 37 CFR 1.48(b) is acknowledged.

6. The Office acknowledges the submission of BLAST searches and the IDS.

7. The declarations filed under 37CFR 1.132 by Mr. Crhristopher Grimaldi, Dr. Paul Polakis and Dr. Avi Ashkenazi have been fully considered.

Claim Objections

8. Claim 11 is objected to because it depends on a rejected claim (claim 6).

Priority

9. Based on the differential mRNA expression in the normal and tumor tissues disclosed in the PCT/US00/23328 filed August 24, 2000, Applicants are entitled to the priority date of August 24, 2000 for nucleic acids only based on the enabling disclosure.

35 USC § 112, second paragraph, withdrawn

10. The rejection of Claims 1-14 and 16-20 under 35 U.S.C. 112, second paragraph, for being indefinite is withdrawn. Applicants' arguments and amendments to the current claims have necessitated the withdrawal of the rejections (4 April 2005).

35 U.S.C. § 112, first paragraph, Written Description withdrawn

11. The rejection of claims 1-6, 9, 10 and 11-14 under 35 U.S.C. § 112, first paragraph, Written Description, is *withdrawn* with respect to the recitation of "extracellular domain" and "signal peptide" because Applicants have amended the claims and described it. Thus, necessitating the withdrawal (4 April 2005).

35 U.S.C. § 112, first paragraph, Enablement withdrawn

12. The rejection of claims 6 and 11-13 under 35 U.S.C. § 112, first paragraph, scope of enablement, is *withdrawn* with respect to the recitation of "extracellular domain" and "signal peptide" because Applicants have amended the claims and described it. Thus, necessitating the withdrawal (4 April 2005).

35 U.S.C. § 101 Lack of Utility, withdrawn

13. The rejection of claims 1-20 under 35 U.S.C. 101, as lacking utility, is withdrawn. Specifically, Applicants assertion that the differentially expressed message can be used as diagnostic tool for melanoma tumor is found to be persuasive.

35 U.S.C. § 112, first paragraph, Enablement withdrawn

14. The rejection of claims 1-20 under 35 U.S.C. § 112, first paragraph, for lacking support for either a specific and substantial asserted utility or a well established utility is withdrawn for reasons indicated above in paragraph 11.

35 USC § 112, first paragraph – Enablement, maintained

15. The rejection of claims 4, 5, 14 and 16-31 under 35 U.S.C. 112, first paragraph, because the specification does not enable one of skilled in the art to which it pertains, or with which it is most closely connected, to make and/or use the invention commensurate in scope with these claims. The reasons for this rejection under 35 U.S.C. § 112, first paragraph, are set forth at pp. 10-14 of the previous Office Action (1 December 2004). Specifically, SEQ ID NO: 129 fragments, polynucleotides that are 95 or 99% identical to such or to the full-length cDNA, nor polynucleotides which hybridize to any of the above because there is no structural or functional information provided in the specification. In addition, the lack of direction/guidance presented in the specification regarding which variants of polynucleotides of SEQ ID NO: 129 encoded proteins would retain the desired activity, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, the absence of working examples directed to variants and the breath of claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Although, Applicants have amended the claims to assert that the nucleic acid is more highly expressed in normal skin tissues compared to melanoma tumor tissue, there is no way of knowing which, if any variants would have the same property of higher expression in the specific tissue. There is no nexus between the degree of homology and regulation of gene expression. Until one identifies a particular variant that

demonstrates a higher expression or not, one of skilled in the art would not know the expression profile of the variant. Modifications to polynucleotides encoding the protein, e.g., by substitutions or deletions, would often result in deleterious effects to overall activity and effectiveness of the protein. Furthermore, it is also well known in the art that hybridization under moderately stringent conditions would yield nucleic acid molecules that are structurally unrelated.

Accordingly, the disclosure fails to enable such a myriad of the claimed nucleic acid molecules that not only vary substantially in length but also in nucleic acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed genus of nucleic acid molecule. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of the molecules embraced by the instant claims. Therefore, the rejections of record are maintained.

35 USC § 112, first paragraph – Written Description, maintained

16. Claims 4, 5, 7, 14 and 16-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention is maintained. The reasons for this rejection under 35 U.S.C. § 112, first paragraph, are set forth at pp. 14-16 of the previous Office Action (1 December 2004). Briefly, the Applicants were not in possession of all or a significant number of polynucleotides that have 95-99% homology to SEQ ID NO: 129 or the full-length cDNA or fragments of SEQ ID NO: 129 nor

polynucleotides which hybridize to any of the above and still retain the function of SEQ ID NO: 129.

Applicants discuss the legal standards applied when evaluating Written Description, including the requirement that written description depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure (pages 24, 4 April 2005). The examiner takes no issue with the discussion of general requirements for evaluating Written Description in this case. However, Applicants have not described or shown possession of all polynucleotides 95-99% homologous to SEQ ID NO: 129 or the full-length cDNA or fragments of SEQ ID NO: 129 nor polynucleotides which hybridize to any of the above, that still retain the function of SEQ ID NO: 129. Nor have Applicants described a representative number of species that have 95-99% homology to SEQ ID NO: 129, such that it is clear that they were in possession of a genus of polynucleotides functionally similar to SEQ ID NO: 129.

As discussed in the previous Office Action (1 December 2004) even a very skilled artisan could not envision the detailed chemical structure of all or a significant number of encompassed polynucleotides, and therefore, would not know how to make or use them. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The claimed product itself is required. Recitation of the phrase "wherein the isolated nucleic acid is more highly expressed in normal skin tissues compared to melanoma tumor tissue," (amended claims, 4 April 2005), is not adequate to describe polynucleotides of the instant invention that have 80-99% homology to the SEQ ID NO: 129 or the full-length

cDNA or fragments of SEQ ID NO: 129 nor polynucleotides which hybridize to any of the above, since there was no reduction to practice to support the amended claims. Specifically, there is no way of knowing which, if any variants would have the same property of higher expression in the specific tissues. There is no nexus between the degree of homology and regulation of gene expression. Until one identifies a particular variant that is highly expressed or not, one of skilled in the art would not know the expression profile of the variant. The mere sequence alone will not allow one of skilled in the art to predict expression. Applicants made no variant polypeptides, and as recited in the current Written Description Guidelines, Applicants must have invented the subject matter that is claimed and must be in "possession" of the claimed genus (Federal Register, 2001, Vol. 66, No. 4, pages 1099-1111, esp. page 1104, 3rd column).

Claim Rejections - 35 USC § 102

17. The rejection of claims 1-20 under 35 U.S.C. 102(b) as being anticipated by Lal et al. (WO200000610A2, Pub. Date 01/2000) is withdrawn because Applicants are entitled to a priority of 8/24/2000, which makes the cited reference 102(e) prior art. Therefore, the pending claims 4-6, 12-14 and 16-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. (WO200000610A2, Pub. Date 01/2000). Applicants have argued that the Applicants are entitled to a priority date of 12/9/99. However, as indicated above in paragraph 9, Applicants are entitled only to priority date of 8/24/2000. Therefore, the claims are rejected under 102(e) over the prior of record. In addition, the newly added claims with fragments sizes are also anticipated because Lal et al. disclose SEQ ID NO: 137 (801bps) which also comprises the full-length coding

sequence. Therefore, claims 4-6, 12-14 and 16-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. (WO200000610A2, Pub. Date 01/2000).

18. Claim 11 will be allowable if written as an independent claim.

19. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 6/05

JANET ANDRES
PRIMARY EXAMINER